

## REMARKS

The foregoing amendment does not involve new matter. Claim 3 was modified to make it dependent only on claim 1. Claims 3, 40, 41 and 46 were amended to change "needleless" to "needlefree" to be consistent with other claim language.

In the International Preliminary Examination Report, claims 1-12, 20, 21, 24-29, 33, 34, 38-55, 59, 60, 62, 66-75, 77-79, 82-88 and 93-111 were noted as being novel and including an inventive step. It is believed that these claims will thus be found patentable during examination of the present application.

The International Preliminary Examination Report took the position that claims 13-19, 22, 23, 30-32, 35-37, 56-58, 61, 63-65, 76, 80, 81 and 92 lacked novelty over U.S. Patent No. 5,549,566 (Elias). This position is traversed, and the comments below are given to show why these claims are patentable over Elias.

First, with respect to claim 56, the claim requires that the needlefree access device have a piston member with an opening that is closed when the top of the piston is forced into the round inlet of the housing, but which allows flow through the opening to the outside of the piston member when the piston member is forced out of the tapered inlet channel. In Elias, when the head portion 50 is forced inwardly, the cannula 18 pokes through the head portion. Flow then goes through openings 70 in the pointed end of the cannula, and through the internal passageway 68, rather than to the outside of the piston member. Hence, Elias does not disclose all of the elements of claim 56. Claim 56, and claims 57-58, 61 and 63-65 dependent thereon, are novel over Elias.

The International Preliminary Examination Report took the position that Elias discloses a method of making a needlefree access device as called for by claim 76. Claim 76 calls for providing a second part comprising a combination outlet section, biasing section and piston section, and constructing the device by securing the second part within the first part. Elias is silent about the order of construction of its various parts. Even if the valve member 16 and cannula 18 of Elias is considered to have a combination outlet section, biasing section and piston section once it is

assembled in the housing, there is no disclosure of assembling the valve member 16 with the cannula 18 prior to placing them in the housing. It is true that col. 5, lines 36-42 discuss how the second end 48 of valve member 16 fits in recess 74 of intermediate portion 64 of cannula 18, but there is no disclosure that this connection is made before the valve member is 16 placed in the housing. In contrast, col. 5, line 41 discusses holding the parts together using sonic welding. Since the valve member 16 is made of rubber or silicone, it cannot be sonically welded to the rigid plastic used to make the cannula. Hence col. 5, line 41 must be referring to the use of sonic welding of the intermediate portion of 64 into the housing 14 as a way of securing the valve member 16 within the recess 74. Since there is no disclosure of the valve member 16 and cannula 18 being assembled together prior to the valve member being inserted into the housing 14, Elias does not meet the limitation of claim 76 requiring providing a second part with the three sections before securing that second part in the housing. Claim 76 goes on to further specify that the needlefree access device is made only from the first and second parts. In Elias the device would be made from assembling more than just two parts. Hence, claim 76 is novel over Elias.

Claim 13 is like claim 76 in requiring that the piston section, biasing section and outlet section are connected together such that they can be handled as one piece when assembled with the housing. As noted above, there is no disclosure in Elias of preassembling the cannula 18 with the valve member 16 prior to inserting the valve member 16 into the housing. Hence, claim 13, and claims 14-19, 22, 23, 30-32, 35-37, 80, 81 and 92 dependent thereon are novel over Elias.

The alleged lack of inventive step of claims 89-91 with respect to Elias and U.S. Patent No. 6,168,137 (Paradis) in the International Preliminary Examination Report is traversed. Claims 89-91 are dependent on claim 13. As noted above, claim 13 is novel over Elias. Paradis does not disclose the concept of a needlefree access device having a piston section, biasing section and outlet section connected together such that they can be handled as one piece before being assembled into the housing. Therefore, even considering Elias combined with Paradis, claim 13 is patentable over the combination. Claims 89-91, being dependent on claim 13, are

therefore also patentable over Elias and Paradis.

An Office Action indicating that all of the claims are patentable is therefore respectfully requested.

Respectfully submitted,

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